

Atty Docket No. 21482-US19
Serial No. 09/987,557
Page 4

REMARKS

Applicants amended claim 10. Those amendments do not add new matter and are supported in the specification, e.g., at page 32, line 15, to page 33, line 5. Claims 11-18 have been cancelled without prejudice or disclaimer. Applicants reserve the right to reintroduce the claims in future prosecution. Claim 10 is pending and under consideration.

Election/Restriction

Applicants have cancelled Claims 11-18 without prejudice or disclaimer.

Priority

Applicants have updated the priority information amending the first paragraph of the specification to include the patent number of the earlier application.

Specification

Applicants thank the Office for providing the guidelines illustrating the preferred layout and content for patent applications. Applicants understand that these are suggested guidelines and not required; therefore no further amendments to the specification are made.

Claim Rejections – 35 USC § 112 second paragraph

Claims 10-12 are rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse the rejections.

The Office asserted that “the intended content of the serum is not defined.” Action at page 4.

Claim 10 has been amended without acquiescence in the rejection and solely to facilitate prosecution and no longer recites “serum.” Therefore, the rejection is now moot. Applicants respectfully request that the Office withdraw the rejection.

The Office asserted that “the intended polypeptide which is/are encoded by DNA of about 7000 to 8,000 base pairs is/are not defined. The intended metes and bounds of the polypeptide are not defined.” Action at page 4.

Claim 10 has been amended without acquiescence in the rejection and solely to facilitate prosecution and now recites that the polypeptide is encoded by a human

Atty Docket No. 21482-US19

Serial No. 09/987,557

Page 5

papillomavirus gene selected from the group consisting of E1, E6, E7, L1 and L2. As these were known genes in the papillomavirus genome, Applicants assert that one skilled in the art would know the intended metes and bounds defined by the claim. In fact, Table 4 of the specification provides the positions of those genes in the HPV 31 genome. Thus, Applicants respectfully request that the Office reconsider and withdraw the rejection.

The Office asserted that "since the specification does not set forth a uniform serum content one cannot be certain of the boundaries of the claimed invention." Action at page 4.

Claim 10 has been amended without acquiescence in the rejection and solely to facilitate prosecution and no longer recites "serum." Therefore, the rejection is now moot. Applicants respectfully request that the Office reconsider and withdraw the rejection.

The Office asserted that the "specification does not set forth any sequences or any fragments of HPV-31 where one can be appraised on their boundaries.

As noted above, the claim only recites genes within the HPV 31 genome that were known and have defined positions in that genome. Therefore, one skilled in the art is apprised of the boundaries of the claim. Applicants respectfully request that the Office reconsider and withdraw the rejection.

Claim Rejections – 35 USC § 112, first paragraph

The Office rejected claims 10-12 as allegedly lacking enablement because deposits of the viruses are required. Action at page 4. The Office noted that the deposit requirement would be satisfied if Applicants submit a declaration stating that HPV-31 "has been deposited under the Budapest Treaty and that the said strains will be irrevocably and without restriction or condition released to the public upon issuance of a patent." Id.

Applicants submit herewith a Declaration Regarding Deposit of Biological Materials providing the requested assurances regarding the availability of the deposited biological materials. The HPV-31 strain was deposited at the National Collection of Cultures of Microorganisms (CNCM) in Paris, France, on November 30, 1984, under the following name and accession number (specification pages 31-32): pBR322/HPV31 Accession No. I-396.

This Declaration was originally filed in the Office in connection with application No. 08/934,659 filed September 22, 1997 (now US Patent No.6,391,539) to which this application claims priority is being attached as Exhibit A. Applicants respectfully request that this rejection be withdrawn.

Atty Docket No. 21482-US19

Serial No. 09/987,557

Page 6

Claim Rejections – 35 USC § 101

Claims 10 is rejected under 35 USC § 101 because the claimed invention is directed to non-statutory matter. Action at page 5. The Office alleged that claim 10 does not distinguish over serum and serum antibodies as they exist naturally and that therefore the claims read on a product of nature. *Id.*

Claim 10 has been amended without acquiescence in the rejection and solely to facilitate prosecution to recite a pharmaceutical composition rather than a serum. Applicants assert that a pharmaceutical composition does not read on a product of nature and therefore is statutory subject matter. Therefore, Applicants respectfully request that the Office reconsider and withdraw the rejection.

Claim Rejections – 35 USC § 112 first paragraph

Claim 10 is rejected under 35 USC § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Action at page 6. The Office argued that “[n]o serum composition which is directed to a product (emphasis added) is/are disclosed.” Action at page 6.

Claim 10 has been amended without acquiescence in the rejection and solely to facilitate prosecution and no longer is directed to a serum. The claim now is directed to a pharmaceutical composition, which is supported in the specification at, e.g., page 32, line 15, to page 33, line 5. Therefore, Applicants respectfully request that the Office withdraw the rejection.

Atty Docket No. 21482-US19
Serial No. 09/987,557
Page 7

Applicants respectfully assert that the present application is in condition for allowance and request that the Office issue a timely Notice of Allowance. A petition for a 3 month extension of time is being filed concurrently with this Response. Please grant any extensions of time required to enter this amendment and charge any additional fees or credit any overpayments to Deposit Account No. 50-0812.

Please direct all future correspondence to:

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Respectfully submitted,

Date: May 5, 2004

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Attachment: Declaration as originally filed with the USPTO in connection with
USSN 08/934,659